

P#28

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re PATENT APPLICATION of  
CATT et al.

Group Art Unit: 1641

Appln. No.: 08/935,717

Examiner: Portner, V.

Filed: September 23, 1997

FOR: TEST KITS AND DEVICES

January 26, 2001

**RESUBMISSION OF INFORMATION DISCLOSURE STATEMENT**

Hon. Commissioner of Patents  
Washington, D.C. 20231

Sir:

Responsive to the Examiner's request, the Applicants herein resubmit a copy of all references earlier submitted to the Patent Office on June 27, 2000 in related application 08/772,522. Applicants filed an Information Disclosure Statement in the present application along with a Request under Rule 97(c) and the appropriate fee of \$240.00 on July 20, 2000. Applicants attach a Form PTO-1449 listing the documents.

This IDS is intended to be in full compliance with the rules, but should the Examiner find any part of its required content to have been omitted, prompt notice to that effect is earnestly solicited, along with additional time under Rule 97(f), to enable Applicant to comply fully.

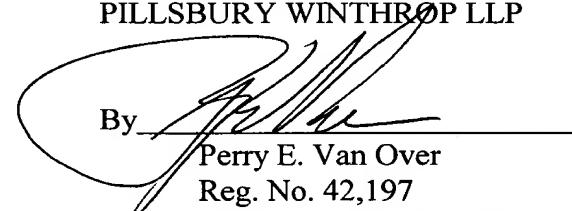
Applicants respectfully request the Examiner to consider each of the documents supplied herewith. It is furthermore respectfully requested that the Examiner confirm the careful and independent consideration in the next official communication by return of an initialed and dated PTO-1449 form in accordance with the provisions of MPEP 609.

CATT et al - Application No. 08/935,717

The Commissioner is hereby authorized to charge any missing or insufficient fee which should have been filed herewith to our Deposit Account No. 03-3975, Order No. 60113/241939.

Respectfully submitted,

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By 

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To:	Atty. Dkt. No.	M#	Client Ref.
		241939	R3248C

INFORMATION DISCLOSURE STATEMENT  
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Examiner: V. PORTNER

Group Art Unit: 1641

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Examiner's Initials*	Document Number	Date MM/YYYY	Name (Family Name of First Inventor)	Class	Sub Class	Filing Date (if appropriate)
AR	3,141,740	07/1964	Wild			
BR	3,406,016	10/1968	FOSTER et al.			
CR	3,406,015	10/1968	Foster			
DR	3,434,801	03/1969	Scherr			
ER	3,436,186	04/1969	Mcsweeney et al.			
FR	3,749,089	07/1973	Derr			
GR	3,875,013	04/1975	MANAUTOU et al.			
HR	3,924,609	12/1975	FRIEDENBERG et al.			
IR	3,926,037	12/1975	Kopito et al.			
JR	3,968,011	07/1976	Manautou et al.			
KR	3,986,494	10/1976	Preti et al.			
LR	3,991,174	11/1976	Grundman			
MR	4,002,056	01/1977	Kopito et al.			
NR	4,010,738	03/1977	Preti et al.			

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					Enclosed	No	Enclose	No
OR	0 011 594 ✓	12/1984	EPO	DES JACQUES				X
PR	0 097 851 ✓	06/1983	EPO	MENKE et al.			X	
QR	0 132 199 ✓	07/1984	EPO	TRAFFORD et al.			X	
RR	0 177 994 ✓	01/1990	EPO	REGAS et al.				X
SR	0 195 207 ✓	01/1986	EPO	FROHN et al.				X
TR	0 225 054 ✓	10/1986	EPO	PERRY et al.			X	
UR	0 286 743 ✓	04/1987	EPO	KOSASKY			X	
VR	0 291 194 ✓	04/1988	EPO	MAY et al.			X	
WR	0 339 092 ✓	12/1987	EPO	MATSUURA			X	
XR	0 367 615 ✓	11/1989	EPO	GLAZE			X	

OTHER (Including in this order Author, Title, Periodical Name, Date, Pertinent Pages, etc.)

YR	Adlercreutz et al., "Prediction of ovulation by urinary estrogen assays", J. Steroid Biochem, 1980, v. 12, pp 395-348		
ZR	Adlercreutz et al., "The measurement of urinary steroid glucuronides as indices of the fertile period in women", J. Steroid Biochem, 1982, v. 17, pp 695,702		
AAR	Albertson et al., "Review Article: The prediction of ovulation and monitoring of the fertile period", Adv. Contracept, v. 3, pp 263-290		
BBR	Baird et al., "Using the ratio of urinary oestrogen and progesterone metabolites to estimate day of ovulation", Statistics in Medicine, 1991, 10, pp 255-266		
CCR	Barnard et al., "A nonseparation, time-resolved fluorimmunoassay to monitor ovarian function and predict potential fertility in women", Fertility and Sterility, 1989, 52(1), pp 60-65		
DDR	Biegelmayer et al., "Evaluation of a simple and fast self-test for urine luteinizing hormone", Fertility and Sterility, 1990, 53(5), pp 842-846		

Examiner

Date Considered:

\*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449 (modified)  
U.S. Department of Commerce  
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Patent and Trademark Office

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ER	4,072,045	02/1978	Kopito			
FR	4,119,089	10/1978	Preti et al.			
GR	4,123,510	10/1978	Banik et al.			
HR	4,148,304	04/1979	Mull			
IR	4,151,831	05/1979	Lester			
JR	4,151,833	05/1979	Polishuk			
KR	4,208,187	06/1980	Givner			
LR	4,232,215	11/1980	Hanley			
MR	4,246,907	01/1981	Bullock			
NR	4,261,371	04/1981	Reading, III			

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OR	0 383 619 ✓	02/1990	EPO	DAVIS et al.			X	
PR	0 385 621 ✓	02/1990	EPO	COLEY et al.			X	
QR	0 424 102 ✓	10/1990	EPO	NISHIMURA			X	
RR	0 470 507 ✓	08/1991	EPO	LO SAPIO et al.			X	
SR	0 476 703 ✓	09/1991	EPO	NISHIMURA et al.			X	
TR	0 498 303 ✓	01/1992	EPO	WEINMANN			X	
UR	0 653 625 ✓	11/1994	EPO	CATT et al.			X	
VR	WO 80/02800 ↗	12/1980	WIPO	OSTER et al.			X	
WR	WO 84/03381 ↗	08/1984	WIPO	AESCHLIMANN	X		X	
XR	WO 87/02774 ↗	05/1987	WIPO	BAKER et al.			X	

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YR	Bischof et al., "Comparison of a rapid, quantitative and automated assay for urinary luteinizing hormone (LH), with an LH detection test, for the prediction of ovulation", Human Reproduction, 1991, 6(4), pp 515-518		
ZR	Bonnar, "Biological methods of identifying the fertile period", Fertility and Sterility, 1984, Eds. Harrison et al., MTP Press, pp 77-92		
AAR	Brown et al., "Appendix 1: Correlations between the mucus symptoms and the hormone markers of fertility throughout reproductive life", The Ovulation Method, 7 <sup>th</sup> Ed., Ed. Bilings, Advocate Press, Melbourne, 1983, pp 99-125		
BBR	Brown et al., "Natural Family Planning", Am. J. Obstet. Gynecol, 1987, 157(4), Part 2, pp 1082-1089		
CCR	Brown et al., "Chemical and homogeneous immunoassay methods for the measurement of estrogens and pregnanediol and their glucuronides in urine", Non-Radiometric Assays: Technology and Application in Polypeptide and Steroid Hormone Detection, Publ. Alan R. Liss Inc., 1988, pp 119-138		
DDR	Brown et al., "New assays for identifying the fertile period", , Int. J. Gynecol Obstet, Suppl. 1, 1989, pp 111-122		

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IR	4,443,851	04/1984	Lin			
JR	4,450,239	05/1984	Chatterton			
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PR	WO 91/15594	10/1991	WIPO	CLOUGH et al.			X	
QR	WO 94/02850	02/1994	WIPO	WELLS et al.			X	
RR	WO 94/04926	03/1994	WIPO	CATT et al.			X	
SR	WO 95/16920	06/1995	WIPO	MARCH et al.			X	
TR	945,670	01/1964	UK				X	
UR	1 203 619	08/1970	UK				X	
VR	2 106 646	04/1983	UK	CHATTERTON			X	
WR	2 045 480	10/1980	UK	OGITA et al.			X	
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YR	Burger, "The physiologica basis of the fertile period", Fertility and Sterility, Eds. Harrison et al., MTP Press, 1984, pp. 51-58			
ZR	Burger, "Estradiol: the physiological basis of the fertile period", Int. J. Gynecol Obstet, Suppl 1, 1989, pp 5-9			
AAR	Campbell, "Methods of monitoring ovarian function and predicting ovulation: summary of a meeting", Research Frontiers in Fertility Regulation, 1985, 3(5), pp 1-16			
BBR	Cardone et al., "Objective and subjective data for fertile period diagnosis in women: comparison of methods", Clin Exp Obst Gyn, XIX, 1992, 1, pp 15-24			
CCR	Cekan et al., "The prediction and/or detection of ovulation by means of urinary steroid assays", Contraception, 1986, 33(4), pp 327-345			
DDR	Collins et al., "The concentrations of urinary oestrone-3-glucuronide, LH and pregnanediol-3a-gluronide as indices of ovarian function", Acta Endocrinologica, 1979, 90, pp 336-347			

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JR	4,753,247	06/1988	Kirsner			
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MR	4,921,808	05/1990	Schneyer et al.			
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OR	2 116 318	09/1983	UK	BAKER et al.			X	
PR	1 048 001	02/1979	Canada				X	
QR	1 183 080	02/1985	Canada	COULSON et al.			X	
RR	2 290 876	06/1976	France					X
SR	2 652 092	03/1991	France	REVOL				X
TR	1 214 438	04/1966	Germany	WILD			X	
UR	28 03 152	07/1979	Germany				X	
VR	28 47 397	05/1980	Germany				X	
WR	3 037 977	05/1982	Germany				X	
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ZR	Collins et al., "Ovulation prediction and detection by the measurement of steroid glucuronides", Proc X Int Congress on Fertility and Sterility, 1981, pp 19-33
AAR	Collines et al., "Biochemical methods for predicting ovulation", Fertility and Sterility, 1984, pp 59-69
BBR	Collins, "Hormonal indices of ovulation and the fertile period", Adv Contracept, 1985, 1, pp 279-294
CCR	Collines, "Biochemical indices of potential fertility", Int J Gynecol Obstet, 1989, Supl. 1, pp 35-43
DDR	Collins et al., "Ovarian morphology, endocrine function and intra-follicular blood flow during the peri-ovulatory period", Human Reproduction, 1991, 6(3), pp 319-324

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QR	3 325 598	01/1985	Germany				X	
RR	3 342 251	05/1985	Germany				X	
SR	3 528 964	02/1987	Germany				X	
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UR	3 609 956	10/1987	Germany				X	
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YR	Collins (1991) <i>Am J Obstet Gynecol</i> , 165(6), p 1994-1996: 'The evolution of reference methods to monitor ovulation'		
ZR	Collins (1992) <i>Biochem Soc Trans</i> , 20, p 234-237: 'Immunochemical tests of potential fertility'		
AAR	Colombo (1989) <i>Int J Gynecol Obstet, Suppl 1</i> , p 13-18: 'Biometrical research on some parameters of the menstrual cycle'		
BBR	Corsan et al <i>Fertility and Sterility</i> , (1990) 53(4), p 591-601: 'Home urinary luteinizing hormone immunoassays: clinical applications'		
CCR	Denari et al (1981) <i>Obstetrics &amp; Gynecology</i> , 58 (1), p 5-9: 'Determination of Ovarian Function Using First Morning Urine Steroid Assays'		
DDR	Djerassi (1990) <i>Science</i> , 1 June 1990, p 1061-1062: 'Fertility Awareness: Jet-Age Rhythm Method?'		

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YR	Fabres et al (1993) <i>Human Reproduction</i> , 8, p 208-210: 'Validation of the dual analyte assay of the oestrone:pregnanediol ratio in monitoring ovarian function'			
ZR	Flynn (1989) <i>Int J Gynecol Obstet, Suppl 1</i> , p 123-127: 'Natural family planning and the new technologies'			
AAR	Fordney-Settlage (1981) <i>Int J Fertil</i> , 26, p 161-169: 'A Review of Cervical Mucus and Sperm Interactions in Humans'			
BBR	France et al (1975) <i>J Reprod Fert, Suppl 22</i> , p 107-120: 'The Detection of Ovulation in Humans and its Applications in Contraception'			
CCR	Garcia et al (1981) <i>Fertility and Sterility</i> , 36(3), p 308-315: 'Prediction of the Time of Ovulation'			
DDR	Gudgeon et al (1989) <i>The Medical Journal of Australia</i> , 152, p 344, 346 and 349: 'Evaluation of the accuracy of the home ovulation detection kit, Clearplan, at predicting ovulation'			

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YR	Hatcher et al (1994) <i>Contraceptive Technology</i> , 16th Revised Edn, Irvington Publishers, NY, p 327-340: 'Fertility Awareness'		
ZR	Ismail et al (1989) <i>Contraception</i> , 39(1), p 53-71: 'An evaluation of the Bioself 110 fertility indicator'		
AAR	Judge et al (1978) <i>Steroids</i> , 31(2), p 175-187: 'Time-Course Relationships between Serum LH, Serum Progesterone and Urinary Pregnanediol Concentrations in Normal Women'		
BBR	Katz et al (1991) <i>Journal of Andrology</i> , January/February 1991, Abstract 29: 'Human Cervical Mucus Properties and Sperm Mucus Interaction during the Proliferative Phase of the Menstrual Cycle'		
CCR	Katz (1991) <i>Am J Obstet Gynecol</i> , 165(6), Part 2, p 1984-1986: 'Human cervical mucus: Research update'		
DDR	Kerin et al (1981) <i>British J Obstet Gynecol</i> , 88(2), p 81-90: 'Morphological and Functional Relations of Graafian Follicle Growth to Ovulation in Women Using Ultrasonic, Laparoscopic and Biochemical Measurements'		

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VR								
WR								
XR								

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ZR	Lewis et al (1993) <i>New Zealand Medical Journal</i> , 28 April 1993, p 165-166: 'Recycling ovulation markers'		
AAR	Lewis et al (1994) <i>Steroids</i> , 59, p 288-291: 'Re-examining steroid hormone metabolites as ovulation markers using monoclonal antibodies'		
BBR	Landgren et al (1980) <i>Acta Endocrinologica</i> , 94, p 89-98: 'Hormonal profile of the cycle in 68 normally menstruating women'		
CCR	May (1989) <i>Proceedings of "Biotech '89" Conference</i> , Blenheim Online Publications, p 291-295: 'Clearblue One Step: adapting technology to the needs of the consumer'		
DDR	Moghissi et al (1972) <i>Am J Obstet Gynecol</i> , 114(3), p 405-418: 'A composite picture of the menstrual cycle'		

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To:	Atty. Dkt. No.	M#	Client Ref.
		241939	R3248C
Applicant: CATT, et al.			
Appln. No.: 08/935,717			
Filing Date: SEPTEMBER 23, 1997			
Examiner: V. PORTNER		Group Art Unit: 1641	

Date: January 26, 2001

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YR	Moghissi (1980) <i>Fertility and Sterility</i> , 34(2), p 89-98: 'Prediction and Detection of Ovulation'		
ZR	Moghissi (1992) <i>Reproductive Endocrinology</i> , 21(1) p 39-55: 'Ovulation Detection'		
AAR	Munro et al (1991) <i>Clin Chem</i> , 37 (6), p 838-844: 'Relationship of Serum Estradiol and Progesterone Concentrations to the Excretion Profiles of Their Major Urinary Metabolites as Measured by Enzyme Immunoassay and Radioimmunoassay'		
BBR	Paz et al (1990) <i>Gynecol Obstet Invest</i> , 29, p 207-210: 'Determination of Urinary Luteinizing Hormone for Prediction of Ovulation'		
CCR	<i>Population Reports</i> , Series 1, No 3, September 1991, p 1-33 - 1-71: 'Periodic Abstinence: How well do new approaches work?'		
DDR	Royston (1982) <i>Biometrics</i> , 38, p 397-406: 'Basal Body Temperature, Ovulation and the Risk of Conception, with Special Reference to the Lifetimes of Sperm and Egg'		

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CCR	Stanczyk et al (1980) <i>Am J Obstet Gynecol</i> , 137(4), p 443-450: 'Direct radioimmunoassay of urinary estrogen and pregnanediol glucuronides during the menstrual cycle'		
DDR	The Economist, March 23, 1991, p 128-129: 'Fertility: Keeping the beat'		

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BBR	WHO Task Force (1980) <i>Am J Obstet Gynecol</i> , 138(4), p 383-390: 'Temporal relationships between ovulation and defined changes in the concentration of plasma estradiol-17beta, luteinizing hormone, follicle-stimulating hormone, and progesterone'			
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AAR	Wright et al (1979) <i>Steroids</i> , 34(4), p 445-457: 'Urinary excretion of estrone glucosiduronate, 17beta-estradiol-17-glucosiduronate, and estriol-16alpha-glucosiduronate. Significance of proportionate differences during the menstrual cycle. I. Probit analysis'		
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